

SEP 17 1996

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Sponsor: Biomet, Inc.
Airport Industrial Park
P.O. Box 587
Warsaw, IN 46581-0578

K960984

Device: SHP Hip System

Classification Name: Hip joint metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3350)

Device Description: The Scientific Hip Prosthesis or SHP Hip System is composed of an anatomic cobalt-chromium alloy femoral stem with a modular head component and an all polyethylene acetabular component. The femoral component is anatomically proportioned, with sizing developed based on a computer analysis of 300 cadaver femurs to achieve a model of actual anatomic variation. The design was determined by Numerical Shape Optimization (NSO) and has been shown to reduce normal and shear stresses in the cement mantle and at the implant/cement and cement/bone interface as compared to other femoral components in an FEM analysis. The proximal surface is roughened to facilitate greater cement adherence. PMMA spacers assist in placement of the stem. The stem is available in seven sizes with left and right configurations. The acetabular component features pegs to ensure a more uniform cement mantle and is available in seven outer diameters.

Indications: Indications for use of the SHP Hip System include: 1) non inflammatory joint disease including osteoarthritis and avascular necrosis, 2) rheumatoid arthritis, 3) correction of functional deformity, 4) revision of failed joint reconstruction, and 5) treatment of nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement which are unmanageable using other techniques.

The device is a single use implant intended for use with bone cement.

Potential Risks: The potential risks associated with this device are the same as with any joint replacement device. These include, but are not limited to:

Reaction to the bone cement	Blood vessel damage	Nerve Damage
Deformity of the joint	Soft tissue imbalance	Bone fracture
Cardiovascular disorders	Delayed wound healing	Infection
Fracture of the cement	Metal sensitivity	Dislocation
Implant loosening/migration	Excessive wear	Hematoma
Fracture of the component		

Substantial Equivalence: In function and overall design, the SHP Hip System is equivalent to many cemented hip components on the market. Commercially available devices for cemented use include:

Rx90 Total Hip System (Biomet, Inc., Warsaw, IN)
Centralign Precoat Hip Prosthesis (Zimmer, Inc., Warsaw, IN)
Ranawat/Burstein Cemented Primary Series (Biomet, Inc., Warsaw, IN)
Buchalter/Fausser Femoral Component (Biomet, Inc., Warsaw, IN)
Premise Total Hip System (Howmedica, Rutherford, NJ)